AUTHORITY: 21 U.S.C. 802, 827(h), 830, 871(b) 890.

SOURCE: 54 FR 31665, Aug. 1, 1989, unless otherwise noted.

§ 1310.01 Definitions.

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13968, Mar. 24, 1997]

§ 1310.02 Substances covered.

The following chemicals have been specifically designated by the Administrator of the Drug Enforcement Administration as the listed chemicals subject to the provisions of this part and parts 1309 and 1313 of this chapter. Each chemical has been assigned the DEA Chemical Code Number set forth opposite it.

(a) List I chemicals

(1) Anthranilic acid, its esters, and its salts	8530
(2) Benzyl cyanide	8735
(3) Ephedrine, its salts, optical isomers, and salts of optical isomers	8113
(4) Ergonovine and its salts	8675
(5) Ergotamine and its salts	8676
(6) N-Acetylanthranilic acid, its esters, and its salts	8522
(7) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers	8317
(8) Phenylacetic acid, its esters, and its salts	8791
(9) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers	1225
(10) Piperidine and its salts	2704
(11) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers	8112
(12) 3,4-Methylenedioxyphenyl-2-propanone	8502
(13) Methylamine and its salts	8520
(14) Ethylamine and its salts	8678
(15) Propionic anhydride	8328
(16) Isosafrole	8704
(17) Safrole	8323
(18) Piperonal	8750
(19) N-Methylephedrine, its salts, optical isomers, and salts of optical isomers (N-Methylephedrine)	8115
(20) N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers	8119
(21) Hydriodic Acid	6695
(22) Benzaldehyde	8256
(23) Nitroethane	6724
(24) Gamma-Butyrolactone (Other names include: GBL; Dihydro-2 (3H)-furanone; 1,2-Butanolide; 1,4-Butanolide; 4-Hydroxybutanoic acid lactone; gamma-hydroxybutyric acid lactone)	2011
(25) Red phosphorus	6795
(26) White phosphorus (Other names: Yellow Phosphorus)	6796
(27) Hypophosphorous acid and its salts (Including ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite and sodium hypophosphite)	6797
(28) N-phenethyl-4-piperidone (NPP)	8332
(29) Iodine	6699
(30) Ergocristine and its salts	8612

(b) List II chemicals:

(1) Acetic anhydride	8519
(2) Acetone	6532
(3) Benzyl chloride	8570
(4) Ethyl ether	6584
(5) Potassium permanganate	6579
(6) 2-Butanone (or Methyl Ethyl Ketone or MEK)	6714
(7) Toluene	6594
(8) Hydrochloric acid (including anhydrous hydrogen chloride)	6545
(9) Sulfuric acid	6552
(10) Methyl Isobutyl Ketone (MIBK)	6715
(11) Sodium Permanganate	6588

(c) The Administrator may add or delete a substance as a listed chemical by publishing a final rule in the FEDERAL REGISTER following a proposal which shall be published at least 30 days prior to the final rule.

(d) Any person may petition the Administrator to have any substance added or deleted from paragraphs (a) or (b) of this section.

(e) Any petition under this section shall contain the following information:

(1) The name and address of the petitioner;

(2) The name of the chemical to which the petition pertains;

(3) The name and address of the manufacturer(s) of the chemical (if known);

(4) A complete statement of the facts which the petitioner believes justifies the addition or deletion of the substance from paragraphs (a) or (b) of this section;

(5) The date of the petition.

(f) The Administrator may require the petitioner to submit such documents or written statements of fact relevant to the petition as he deems necessary in making a determination.

(g) Within a reasonable period of time after the receipt of the petition, the Administrator shall notify the petitioner of his decision and the reason therefor. The Administrator need not accept a petition if any of the requirements prescribed in paragraph (e) of this section or requested pursuant to paragraph (f) of this section are lacking or are not clearly set forth as to be readily understood. If the petitioner desires, he may amend and resubmit the petition to meet the requirements of paragraphs (e) and (f) of this section.

(h) If a petition is granted or the Administrator, upon his own motion, proposes to add or delete substances as listed chemicals as set forth in paragraph (c) of this section, he shall issue and publish in the FEDERAL REGISTER a proposal to add or delete a substance as a listed chemical. The Administrator shall permit any interested person to file written comments regarding the proposal within 30 days of the date of publication of his order in the FEDERAL REGISTER. The Administrator will consider any comments filed by interested persons and publish a final rule in accordance with his decision in the matter.

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 48733, Sept. 26, 1991; 57 FR 43615, Sept. 22, 1992; 60 FR 19510, Apr. 19, 1995; 60 FR 32460, June 22, 1995; 62 FR 5917, Feb. 10, 1997; 65 FR 21647, Apr. 24, 2000; 65 FR 47316, Aug. 2, 2000; 66 FR 52675, Oct. 17, 2001; 71 FR 60826, Oct. 17, 2006; 72 FR 20046, Apr. 23, 2007; 72 FR 35391, July 2, 2007; 72 FR 40238, July 24, 2007; 76 FR 17781, Mar. 31, 2011]

§ 1310.03 Persons required to keep records and file reports.

(a) Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction as specified by § 1310.04 and file reports as specified by § 1310.05. However, a non-regulated person who acquires listed chemicals for internal consumption or ''end use'' and becomes a regulated person by virtue of infrequent or rare distribution of a listed chemical from inventory, shall not be required to maintain receipt records of listed chemicals under this section.

(b) Each regulated person who manufactures a List I or List II chemical shall file reports regarding such manufacture as specified in Section 1310.05.

(c) Each regulated person who engages in a transaction with a nonregulated person or who engages in an export transaction that involves ephedrine, pseudoephedrine, phenylpropanolamine, or gamma-hydroxybutyric acid, including drug products containing these chemicals, and uses or attempts to use the Postal Service or any private or commercial carrier must file monthly reports of each such transaction as specified in § 1310.05 of this part.

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 8277, Feb. 28, 1991; 61 FR 14023, Mar. 29, 1996; 67 FR 14861, Mar. 28, 2002; 68 FR 57804, Oct. 7, 2003; 70 FR 294, Jan. 4, 2005]

§ 1310.04 Maintenance of records.

(a) Every record required to be kept subject to § 1310.03 for a List I chemical, a tableting machine, or an encapsulating machine shall be kept by the regulated person for 2 years after the date of the transaction.

(b) Every record required to be kept subject to Section 1310.03 for List II chemical shall be kept by the regulated person for two years after the date of the transaction.

(c) A record under this section shall be kept at the regulated person's place of business where the transaction occurred, except that records may be kept at a single, central location of the regulated person if the regulated person has notified the Administration of